EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

Digitally signed by Iarovoi Petru
Date: 2022.11.11 19:20:09 EET
Reason: MoldSign Signature
Location: Moldova

Products:
- Analgetic control kits
- Angiographic accessories kits
- Aspiration catheters
- Balloon catheters
- Biliary prosthesis, catheters and kits
- Catheters and kits for dialysis
- Catheters for oxygen rhinoscopic administration
- Central venous pressure measuring kits
- Connectors
- Cystostomy catheters and kits
- Dilating catheters and dilators
- Drainage catheters and kits
- Drains
- Embolectomy and thrombectomy catheters
- Embolization catheters

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 84949468-50

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH Eingestellt

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Extenders
- Feeding catheters
- Flat antibacterial filters
- Guide wires
- Gynecology catheters and kits
- Insemination catheters
- Introducers
- Kits for stent introduction
- Nephrostomy catheters and kits
- Pediatric catheters
- Puncture kits
- Rotating Y type adapters with and without valve
- Scalpels
- Stopcock manifolds and stopcocks
- Syringes
- Thermodilution kits
- Thrombolysis catheters and kits
- Treatment needles
- Ureteral catheters
- Urological catheters
- Vessel compression tourniquets
- Vessel irrigation catheters

Report No.: 84949468-50

Effective date: 2021-05-12

Expiry date: 2024-05-26

Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer:
BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Vessel slings
- Sets for venous insufficiency treatment
- Infusion microcatheters
- Support catheters

For the following medical devices, the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Aspirators
- Blockers
- Bottles, containers for aspiration
- Dilatation catheters for salivary duct
- Endoscopic balloon dilation catheters
- Guide wire grips
- Guide wire introduction tubes
- Insemination catheter universal luer lock caps
- Larynx anesthesia catheters
- Luer lock caps
- Mandrins
- Pushers
- Redon plugs

Report No.: 84949468-50

Effective date: 2021-05-12

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Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH Prüfstelle

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EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

- Radial artery compression tourniquet kits
- Stents for salivary ducts
- Suction connectors
- Universal hubs luer lock

Replaces EC Certificate, Registration No.: HD 60144654 0001

Report No.: 84949468-50

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TÜV Rheinland LGA Products GmbH Zertifizierstelle TÜVRheinland®

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1023580-1

Manufacturer: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	BALTON Sp. z o.o. ul. Nowy Świat 7/14 00-496 Warszawa Poland	Activity: Administration.
/02	BALTON Sp. z o.o. ul. Modlińska 294 03-152 Warszawa Poland	Activity: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
/03	BALTON Sp. z o.o. ul. Strzelnicza 3 18-300 Zambrów Poland	Activity: Production of disposable medical devices.
/04	BALTON Sp. z o.o. ul. Topolowa 23 05-119 Łajski Poland	Activity: Production of components and packaging materials for disposable medical devices and EO gas sterilization service according to EN ISO 11135:2014 standard.

Report No.: 84949468-50

Effective date: 2021-05-12

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Issue date: 2021-05-12

TÜV Rheinland LGA Products GmbH

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Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

RA/24/2022

Declaration of Conformity

Revision 2

BALTON Sp. z o. o.

ul. Nowy Świat 7/14

00-496 Warszawa

POLAND

SRN: PL-MF-000010568

declares under his sole responsibility that the products mentioned in the product list attached to this declaration are labelled with the CE safety mark. The granting of the mark is confirmed by certificates

Device	EC Certificate	EC Design Certificate
Anaesthesia sets	145084-21-03-25	145085-21-03-25

issued by the CE Certiso Ltd. certification body in Budakeszi, Hungary, bearing the identification mark of the notified body - 2409. These products conform the required technical documentation in accordance with the requirements of Annex II of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and the amendment to Directive 2007/47/EC.

In addition, we declare that the distributed CE marked products, classified as Class III Rule 6, comply with the requirements of the applicable European Council Directive.

This declaration is supported by the Quality System developed base on the harmonized standards:

- EN ISO 13485:2016, Certificate no. SX 1023580-1 Notified Body TÜV Rheinland LGA Products GmbH.

This declaration of conformity is valid for all products bearing the CE mark and manufactured in the locations listed below:

Headquarters:	ul. Nowy Świat 7/14, 00-496 Warszawa, Poland
Manufacturing plants:	ul. Modlińska 294, 03-152 Warszawa, Poland
	ul. Topolowa 23, 05-119 Łajski, Poland

PRODUCT LIST

Products included in the list below are covered by the Declaration of Conformity no RA/24/2022. All CE-marked products included in the list will be distributed by BALTON Sp. z o. o. in accordance with the provisions of the European Council Directive 93/42/EEC of 14.06.1993 concerning medical devices and the amendment to the Directive 2007/47/EC.

The list identifies products by name and model and Basic UDI-DI.

Product type according CE certificate and intended purpose	Type	Model	References	EMDN	Basic UDI-DI
Anaesthesia sets / Epidural anaesthesia sets are intended for the introduction of analgetic agents or opiate	Epidural anaesthesia set small	ZZOMA, ZZOMAS, ZZOMASN, ZZOMASSN, ZZOMAEM, ZZOMASEM, ZZOMASNEM, ZZOMASSNE, Where A - Size (16G; 17G; 18G; 19G) S – Soft tip SN – Low resistance siringe **EM** - Catheter fixing element	**According to the Annex I**	**A01030103 /** COMBINED EPIDURAL AND SPINAL ANAESTHESIA NEEDLES AND KITS	5901297ANAESTHESIA SETSYK
	Epidural anaesthesia set advanced	ZZORA, ZZORAS, ZZORAEM, ZZORASEM Where A - Size (16G; 17G; 18G; 19G) S - Soft tip **EM** - Catheter fixing element	**According to the Annex II**		
	Combined anaesthesia set advanced	ZZORAIB, ZZORASIB ZZORAIBEM, ZZORASIBEM Where A - Size (16G; 18G) S - Soft tip B – Spinal	**According to the Annex III**		

		needle size and length (IPPS26G / 130; IPPS 26G / 90; IPPW 26G / 90; IPPS 27G / 130; IPPS 27G / 120; IPPS 27G / 90; IPPW27G / 120; IPPW27G / 90; IPPS26G / 130; IPPS26G / 90; IPPW26G / 90; IPPS27G / 130; IPPS27G / 120; IPPS27G / 90; IPPW27G / 120; IPPW27G / 90)			
	Combined anaesthesia set small	ZZKA Where A - Size (16G; 18G)	**According to the Annex IV**		
	Epidural anaesthesia set with accessories for spinal and combined anaesthesia	ZZORAD, ZZORASD Where A - Size (18G; 19G; 20G; 22G) S – Soft tip D – Additional Elements (sterile field, bowl, gauze swab, tray, sponge, system for catheter fixing)	**According to the Annex V**		
	Tuohy needle	ITA Gdzie A - Size (16G; 17G; 18G; 19G)	**According to the Annex VI**	**A01030102/** EPIDURAL ANAESTHESIA NEEDLES AND KITS	
	Epidural catheter	KEAS Where A - Size (18G; 19G; 20G; 22G) S - Soft tip	**According to the Annex VII**	**N02010102/** PERIDURAL / EPIDURAL CATHETERS FOR CONTINUOUS ANALGESIA AND KITS	

19th April 2022
Warsaw, Poland

Regulatory Affairs Director

Person responsible for regulatory compliance (PRRC)

ANNEX I - Epidural anaesthesia set small

ZZOM16G, ZZOM17G, ZZOM18G, ZZOM19G,

ZZOM16GS, ZZOM17GS, ZZOM18GS, ZZOM19GS,

ZZOM16GSN, ZZOM17GSN, ZZOM18GSN, ZZOM19GSN,

ZZOM16GSSN, ZZOM17GSSN, ZZOM18GSSN, ZZOM19GSSN,

ZZOM16GEM, ZZOM17GEM, ZZOM18GEM, ZZOM19GEM,

ZZOM16GSEM, ZZOM17GSEM, ZZOM18GSEM, ZZOM19GSEM,

ZZOM16GSNEM, ZZOM17GSNEM, ZZOM18GSNEM, ZZOM19GSNEM,

ZZOM16GSSNEM, ZZOM17GSSNEM, ZZOM18GSSNEM, ZZOM19GSSNEM.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1023580-1

Organization: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

Scope: Design and development, production and distribution of sterile, disposable medical devices for dialysis and hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
Provision of EO sterilization service according to EN ISO 11135:2014 standard.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84951149-20
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1023580-1

Organization: BALTON Sp. z o.o.
ul. Nowy Świat 7/14
00-496 Warszawa
Poland

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	BALTON Sp. z o.o. ul. Nowy Świat 7/14 00-496 Warszawa Poland	Administration.
/02	BALTON Sp. z o.o. ul. Modlińska 294 03-152 Warszawa Poland	Design and development, production and distribution of sterile, disposable medical devices for dialysis, hemodialysis, radiology, cardiology, urology, anesthesiology, gynecology and general surgery.
/03	BALTON Sp. z o.o. ul. Strzelnicza 3 18-300 Zambrów Poland	Production of disposable medical devices.
/04	BALTON Sp. z o.o. ul. Topolowa 23 05-119 Wieliszew-Łajski Poland	Production of metal elements for medical devices. Provision of EO sterilization service according to EN ISO 11135:2014 standard.

Report No.: 84951149-20
Effective date: 2021-12-01
Expiry date: 2023-12-02
Issue date: 2021-12-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02